Supplement to

INFORMATION LETTER

NATIONAL CANNERS ASSOCIATION

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FDA REGULATION UNDER FOOD ADDITIVE LAW

(from Federal Register of Feb. 27, 1960)

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart A—Definitions and Procedural and Interpretative Regulations

EXTENSION OF EFFECTIVE DATE OF STATUTE FOR CERTAIN SPECIFIED FOOD ADDITIVES

The Commissioner of Food and Drugs, pursuant to the authority provided in the Federal Food, Drug, and Cosmetic Act (sec. 6(c), Public Law 85-929; 72 Stat. 1788; 21 U.S.C., note under sec. 342) and delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), hereby authorizes the use in foods of certain additives for which tolerances have not yet been established or petitions therefor denied.

1. Section 121.86 (25 F.R. 343, 404, 1074) is amended by changing the section headnote to read as set forth below and by adding thereto the following new items:

§ 121.86 Extension of effective date of statute for certain specified food additives as direct additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in food, under certain specified conditions, for a period of one year from March 6, 1960, or until regulations shall have been issued establishing or denying tolerances or exemptions from the requirement of tolerances, in accordance with section 409 of the act, whichever occurs first:

Product	Limits	Specified uses or restrictions
Annatto colorants	35 parts per million (based on annatto solids).	As coloring in foods.
Butylated hydroxyanisole and/or butylated hydroxytoluene.	0.001 percent (combined total)	As an antioxidant in dry mixes for making prepared foods.
Butylated hydroxyanisole and/or butylated hydroxytoluene, and/or propyl gallate.	0.005 percent (combined total)	As antioxidants in breakfast cereals.
Copper pyrophosphate	0.005 percent of copper in total daily ration.	In mineral mixtures used in concentrated animal feeds.
Cottonseed flour (cooked and partially defatted).	5 percent	In bakery products.
3,5-Diiodosalicylic acid	300 parts per million	In salt blocks for animal use.
Ethyl cellulose	35 percent by weight	In dry vitamin preparations for animal feed and human food use.
Fumaric acid	0.3 percent	In foods as an acidulant, flavoring, and leavening agent.
Polyoxyethylene (20) sorbitan monooleate.	0.1 percent	In frozen desserts (other than water ices), as an emulsifier.
Do	do	In imitation ice cream, as an emulsifier.
Do	0.05 percent	In pickles, as an emulsifier.
Do		As an emulsifier in flavored foods when used at rate not to exceed nine parts by weight per one part of flavor.
Do	0.475 percent	In cakes, as an emulsifier.
Do	0.45 percent	In cake icing, as an emulsifier.
Do	0.5 percent	In confectionery coating, as an emulsifier.
Do	0.2 percent	In sugar confectionery pan coatings, as an emulsifier.
Do	0.4 percent	In whipped topping, as an emulsifier.
Do		As an emulsifier in flavored foods when used at rate not to exceed nine parts by weight per one part of flavor.
Do	0.1 percent	In frozen desserts (other than water ices), as an emulsifier.
Do	do	In imitation ice cream, as an emulsifier.
Quinine sulfate	0.01 percent	As flavoring agent in carbonated beverages.
Sorbitan monostearate		As an emulsifier in flavored foods when used at rate not to exceed nine parts by weight per one part of flavor.
Sorbitan monostearate in combination with polyoxyethylene (20) sorbitan monostearate.	0.475 percent	In cakes, as an emulsifier.
Do	1.0 percent	In confectionery coating, as an emulsifier.
Do	0.4 percent	In whipped topping, as an emulsifier.

2. Section 121.86 is further amended by deleting therefrom the following items which are added to § 121.87:

Product	Limits	Specified uses or restrictions
Coumarone-indene resin	200 parts per million	In coating on citrus fruits.
Dibutyl phthalate	2.17 percent	In nitrocellulose-coated, heat-sealing cellophane for packaging foods.
Dicyclohexyl phthalate	do	Do.
Inorganic bromides	50 parts per million	In processed foods from methyl bromide fumigation.
Maleic acid	0.40 percent	In nitrocellulose-coated, heat-sealing cellophane for packaging foods.
Pentaerythritol tetrastearate	0.09 percent	Do.
Polymers of pimaric and abietic acids and/or rosin constituents.	0.64 percent	Nitrocellulose-coated, heat-sealing cellophane for packaging foods.
Titanium dioxide N.F	20 percent	In adhesives for food packages.

3. Part 121 is amended by adding thereto the following new section:

§ 121.87 Extension of effective date of statute for certain specified food additives as indirect additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in connection with the production, packaging, and storage of food products, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued in accordance with section 409 of the act, whichever occurs first. The extensions are granted under the condition that a minimum quantity of the additive will be incorporated in the food, consistent with good manufacturing practice.

(a) *General list.*

Product	Limits	Specified uses or restrictions
Bromides, inorganic	50 parts per million	In processed foods from methyl bromide fumigation.
Carbon tetrachloride		As a fumigant, in food plant use.
Coumarone-indene resin	200 parts per million	In coating on citrus fruits.
Chloropicrin		As a fumigant, in food plant use.
Dibutyl phthalate		Not to exceed 2.17 percent in nitrocellulose-coated, heat-sealing cellophane for packaging foods.
Dicyclohexyl phthalate		Do.
Ethylene dibromide		As a fumigant in food plant use.
Ethylene dichloride		Do.
Maleic acid		Not to exceed 0.60 percent in nitrocellulose-coated, heat-sealing, cellophane for packaging foods.
Mineral oil		Not to exceed 2 percent in fiber bags to contain dry foods.
Mono fatty acid ester of polyethylene glycol.		Not to exceed 0.5 percent in film wrappings for food.
Pentaerythritol tetrastearate		Not to exceed 0.09 percent in nitrocellulose-coated, heat-sealing, cellophane for packaging foods.
Piperonyl butoxide		As a fumigant in food plant use.
Polymers of pimaric and abietic acids and/or rosin constituents.		Not to exceed 0.64 percent in nitrocellulose-coated, heat-sealing cellophane for packaging foods.
Polyoxyethylene (20) sorbitan monooleate.		Not to exceed 1.48 percent in film wraps for meat, as an emulsifier.
Propylene oxide		As a fumigant in foods.
Pyrethrins		Do.
Tetraethylene pentamine		Not to exceed 1.77 percent in coatings for food-storage containers.
Titanium dioxide		Not to exceed 20 percent in adhesives for food packages.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since extensions of time, under certain conditions, for the effective date of the food additives amendment to the Federal Food, Drug, and Cosmetic Act were contemplated by the statute as a relief of restrictions on the food processing industry.

Effective date. This order shall be effective on the date of publication in the FEDERAL REGISTER.

(Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371. Interprets or applies 72 Stat. 1786; 21 U.S.C., note under section 342)

Dated: February 19, 1960.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

(from Federal Register of March 1, 1960)

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart A—Definitions and Procedural and Interpretative Regulations

Subpart E—Substances for Which Prior Sanctions Have Been Granted

PAPER AND PAPERBOARD; EXTENSIONS OF EFFECTIVE DATE; PRIOR SANCTIONS

Pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 409, 701, 72 Stat. 1785, 1788, 52 Stat. 1055, as amended 72 Stat. 948; 21 U.S.C., note under sec. 342, 348, 371), and delegated to the Commissioner of Food and Drugs by the Secretary (23 F.R. 9500): *It is ordered*, That the food additive regulations (24 F.R. 2434; 21 CFR 121.87; 21 CFR 121.2001 (25 F.R. 866) be amended as set forth below:

1. In Subpart A, § 121.87 is amended by adding thereto the following new paragraph (b):

§ 121.87 Extension of effective date of statute for certain specified food additives as indirect additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in connection with the production, packaging, and storage of food products, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued in accordance with section 409 of the act, whichever occurs first. The extensions are granted under the condition that a minimum quantity of the additive will be incorporated in the food, consistent with good manufacturing practice.

* * * * *

(b) *Substances migrating from paper and paperboard products used in food packaging*—(1) *Defoaming agents.*

Aliphatic hydrocarbon fractions of petroleum.
Castor oil.
Cetyl alcohol.
Coconut alkylolamide.
Coconut oil, sulfonated.
Cottonseed fatty acid.
Cyclohexanol.
Diethamolamine stearate.
Ethylenediamine tetraacetic acid tetrasodium salt.
Formaldehyde.
Glyceryl monohydroxystearate.
Hexadecanol.
Hexylene glycol.
Hydrogenated fish oil.
Isobutanol.
Isopropanol.
Kerosene, completely aliphatic.
Kerosene oil.
Kerosene oil, deodorized.
Lauryl alcohol.
Lignin sulfonate sodium salt.
Marine oil fatty acid soaps (hydrogenated).
Methyl oleate.
Methyl oleate-palmitate mixture.
Methyl tallowate.
Mineral oil.
Mustardseed oil, sulfated.
Myristyl alcohol.
Naphtha.
Oleic acid, animal source.
Oleic acid, sulfated.
Oleic acid, vegetable source.
Oil paraffin.
Oil paraffin, pale paraffin oil.
Parachlorometacresol.
Paraffin wax.
Peanut oil, sulfated.
Pentaerythritol monostearate.
Polyalkylene glycol ether.
Polyethylene (slightly oxidized).
Polyethylene glycol, ester of rosin (15 M).
Polyethylene glycol, ester of rosin octylphenol.
Polyethylene glycol 200, monotallate.
Polyethylene glycol 200, monooleate.
Polyethylene glycol 200, monostearate.
Polyethylene glycol 400, ditallate.
Polyethylene glycol 400, dioleate.
Polyethylene glycol 400, distearate.
Polyethylene glycol 400, monococoate.
Polyethylene glycol 400, monolaurate.
Polyethylene glycol 400, monooleate.
Polyethylene glycol 400, monostearate.
Polyethylene glycol 400, monotallate.
Polyethylene glycol 400, tallow diester and glycerides.
Polyethylene glycol 450, monostearate.
Polyethylene glycol 600.
Polyethylene glycol 600 monooleate.
Polyethylene glycol 600, monoricinoleate.
Polyglycol ether of tridecyl alcohol.
Polyoxyethylene sorbitan monostearate.
Rice bran oil.
Rice bran oil, sulfated.
Ricinoleate (butyl).
Ricinoleate (methyl).
Sodium stearate, technical grade.
Sorbitan monostearate.
Sorbitan tristearate.
Sperm oil, sulfated (75%).
Stearic acid.
Stearic acid, single pressed.
Stearic acid, double pressed.
Stearic acid, rubber grade.
Stearic palmitic acids, 63:29.
Stearyl alcohol, technical grade, approximately 65%–80% stearyl and 20%–35% cetyl.
Tall oil fatty acid, methyl ester.
Tall oil, refined.
Tallow, alcohol, hydrogenated.
Tallow, blown (oxidized).
Tallow.
Tallow fatty acids.
Tallow fatty acids, hydrogenated.
Tallow, hydrogenated.
Tallow, monoglyceride.
Tallow, propylene glycol ester.
Tallow, sodium soap.
Tallow, sulfated (75%).
Tallow, sulfated (80%).
Tallow, sulfonated (50%).
Tallow, unbleached.
Triethanolamine (98%).
Trilsopropanolamine.
Zinc stearate.

(2) *Rosin and rosin derivatives.* As incidental additives to food from the use as components of adhesives, wax and other coatings, plasticizers, inks, lacquers, sizings, paper finishers, defoaming and dispersing agents, intended for use in the manufacture of paper and paperboard for the packaging of food.

Wood rosin, gum rosin, and tall oil rosin and the dimers thereof, and these substances as modified by the following reactants:
Bisphenol-formaldehyde.
Ethylene glycol.
Formaldehyde.
Fumaric acid.
Glycerin.
Hydrogen.
Maleic anhydride.
Methanol.
Pentaerythritol (double-crystallized).
Phthalic anhydride.
Sulfuric acid.
Triethylene glycol.

(3) *Miscellaneous chemicals and substances used in the manufacture of paper and paperboard for food packaging.* As incidental additives to food from the use as components of adhesives, wax, and other coatings, plasticizers, inks, lacquers, sizings, paper finishes, slime-control agents, dispersing agents, and/or other uses:

Acrylic and methacrylic esters (aqueous emulsions of polymers).
Animal glue.
Anionic polyacrylamide.
bis(1,4-Bromoacetoxy)-2-butene.
Carbon black prepared by the "impingement" or "channel" process.
Dibutyl phthalate.
Dicyclohexylphthalate.
Dicyandiamide.
Dimethyl polysiloxane polymer.
Dioctyl sodium sulfosuccinate.
Hydroxyethylcellulose.
β-Hydroxyethyl pyridinium salt of 2-mercaptobenzothiazole.
Hydroxyethyl starch.
Mixture of the ketene dimers of palmitic and stearic acids.
Monosulfonated naphthalene.
Oxidized starch.
Pentaerythritol ester of maleic anhydride.
Polyamide-epichlorohydrin resin.
Polyoxyethylated castor oil.
Polyoxyethylated oleyl alcohol.
Polyvinyl alcohol.
Sodium dodecylbenzene sulfonate.
Sodium lauryl sulfate.
Sodium ligninsulfonate (sodium lignosulfonate).
Sodium nitrate.
Sodium salt of naphthalene sulfonic acid condensed with formaldenyde.
Sodium salts of dimethyl dithiocarbamic acid and 2-mercaptobenzothiazole.
Triethylene glycol polyester of phthalic anhydride (modified).
Vinyl acetate dibutyl maleate copolymer.
Zinc dimethyldithiocarbamate in combination with zinc salt of 2-mercaptobenzothiazole.

2. In Subpart E, § 121.2001 is amended by adding the following new paragraph (b):

§ 121.2001 Substances for which prior sanctions have been granted.

* * * * *

(b) *Substances used in the manufacture of paper and paperboard products used in food packaging.*

Aliphatic polyoxyethylene ethers.*
1-Alkyl (C_8-C_{18})-amino-3-aminopropane monoacetate.*
Borax or boric acid for use in adhesives, sizes, and coatings.*
Butadiene-styrene copolymer.
Chromium complex of perfluoro-octane sulfonyl glycine for use on paper and paperboard which is waxed.*
Disodium cyanodithioimidocarbamate with ethylene diamine and potassium *N*-methyl dithiocarbamate and/or sodium 2-mercaptobenzothiazole (slimicides).*
Ethyl acrylate and methyl methacrylate copolymers of itaconic acid or methacrylic acid for use only on paper and paperboard which is waxed.*
Hexamethylene tetramine as a setting agent for protein, including casein.*
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2-alkyl (C_5-C_{11}) imidazolinium chloride.*
Itaconic acid (polymerized).
Melamine formaldehyde polymer.
Methyl acrylate (polymerized).
Methyl ethers or mono-, di-, and tripropylene glycol.*
Myristo chromic chloride complex.
Nitrocellulose.
Polyethylene glycol 400.
Polyvinyl acetate.
Potassium pentachlorophenate as a slime control agent.*
Potassium trichlorophenate as a slime control agent.*
Pyrethrins in combination with piperonyl butoxide in outside plies of multiwall bags.*
Resins from high and low viscosity polyvinyl alcohol for fatty foods only.
Rubber hydrochloride.
Sodium pentachlorophenate as a slime control agent.*
Sodium trichlorophenate as a slime control agent.*
Stearato-chromic chloride complex.
Titanium dioxide.*
Urea formaldehyde polymer.
Vinylidine chlorides (polymerized).

*Under the conditions of normal use, these substances would not reasonably be expected to migrate to food, based on available scientific information and data.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since extensions of time, under certain conditions, for the effective date of the food additives amendment to the Federal Food, Drug, and Cosmetic Act were contemplated by the statute as a relief of restrictions on the food-processing industry and since the listing of the substances on which prior sanctions have been granted implements the regulation (§ 121.3) previously promulgated, relieves the Food and Drug Administration from the necessity of advising of individual sanctions upon request of the affected industry, and relieves the industry from the necessity of requesting advice concerning the use of substances for which sanctions have already been granted.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER, since interested persons will benefit by the earliest effective date, and I so find.

(Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371. Interprets or applies secs. 201(s), 409, 72 Stat. 1784 et seq.; 21 U.S.C. 321(s), 348)

Dated: February 19, 1960.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 60-1762; Filed, Feb. 29, 1960; 8:45 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

FOOD ADDITIVES; SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Chemicals and Substances Used in Manufacture of Paper and Paperboard Products for Food Packaging

In accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 409, 701, 72 Stat. 1785, 52 Stat. 1055, as amended; 21 U.S.C. 348, 371), the Commissioner of Food and Drugs, pursuant to the authority delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), proposes to add the following substances that may be found in paper and paperboard products used in food packaging to the list of substances generally recognized as safe (Subpart B, § 121.101 (24 F.R. 9368; 25 F.R. 405)):

§ 121.101 Substances that are generally recognized as safe.

* * * * *

(f) Substances migrating to food from paper and paperboard products used in food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Acetic acid.
Alum (double sulfate of aluminum and ammonium potassium, or sodium).
Aluminum hydroxide.
Aluminum oleate.
Aluminum palmitate.
Ammonium chloride.
Ammonium hydroxide.
Calcium chloride.
Calcium hydroxide (lime).
Calcium sulfate.
Casein.
Cellulose acetate.
Clay (kaolin).
Copper sulfate.
Cornstarch.
Corn sugar (sirup).
Dextrin.
Diatomaceous earth filler.
Ethyl cellulose.
Ethyl vanillin.
Ferric sulfate.
Ferrous sulfate.
Formic acid or sodium salt.
Glycerin.
Guar gum.
Invert sugar.
Iron, reduced.
Locust bean gum (carob bean gum).
Magnesium carbonate.
Magnesium chloride.
Magnesium hydroxide.
Magnesium sulfate.
Methyl and ethyl acrylate.
Mono and diglycerides from glycerolysis of edible fats or oils.
Oleic acid.
Oxides of iron.
Potassium sorbate.
Propionic acid.
Propylene glycol.
α-Protein.
Silicon dioxides.
Pulps from wood, straw, bagasse, or other natural sources.
Soap (sodium oleate, sodium palmitate).
Sodium aluminate.
Sodium carbonate.
Sodium chloride.
Sodium hexametaphosphate.
Sodium hydrosulfite.
Sodium hydroxide.
Sodium phosphoaluminate.
Sodium silicate.
Sodium sorbate.
Sodium sulfate.
Sodium thiosulfate (0.1 percent in salt).
Sodium tripolyphosphate.
Sorbitol.
Sulfamic acid.
Sulfuric acid.
Starch, acid modified.
Starch, pregelatinized.
Starch, unmodified.
Sucrose.
Talc.
Urea.
Vanillin.
Zinc hydrosulfite.
Zinc sulfate.

The Commissioner of Food and Drugs hereby offers an opportunity to all interested persons to present their views in writing with reference to this proposal to the Hearing Clerk, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington 25, D.C., within 30 days from the date of publication of this notice in the FEDERAL REGISTER. Comments may be accompanied by a memorandum or brief in support thereof, and it is requested that all comments be submitted in quintuplicate.

Dated: February 19, 1960.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 60-1761; Filed, Feb. 29, 1960; 8:45 a.m.]